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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,790	05/11/2006	Tushar A. Kshirsagar	C1271.70032US01	6742
23628	7590	11/02/2009	EXAMINER	
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206			DESAI, RITA J	
		ART UNIT	PAPER NUMBER	
		1625		
		MAIL DATE	DELIVERY MODE	
		11/02/2009	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/595,790	KSHIRSAGAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 August 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2,4,5,7-10,13-16,19-29 and 35-72 is/are pending in the application.  
 4a) Of the above claim(s) 7-10,13,15,16,36-38,50-64 and 67-72 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

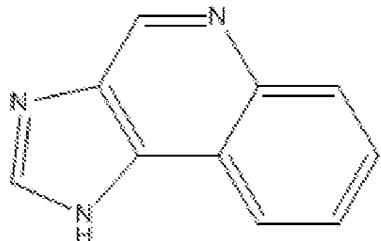
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/20/09, 8/11/06</u> .  | 6) <input type="checkbox"/> Other: _____ .                        |

### DETAILED ACTION

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are in the elected group drawn to compounds and compositions wherein Ra and Rb from a ring, i.e. drawn to tricyclic ring compounds which



*1H-imidazo[4,5-c]quinoline*

is given by . Group I, drawn to compounds wherein RA and RB together with the ring form a *1H-imidazo[4,5-c]quinoline* and no additional heterocycle is present, and compositions

Claims pending, 2, 4, 5, 7-10, 13-16, 19-29, 35-72.

Claims 7-10, 13, 15, 16, 36-38, 50-64, 67-72 are withdrawn.

### *Priority*

The priority to the provisional application 60/520,215 is acknowledged.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R, R3 on the ring to be H m and

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n =1( formula IIIa) and R1 to be an alkyl or an alkyl-OH, or an alkyl NH-R , does not reasonably provide enablement for 1)R1 to be all the various groups nor for2) R2a , Y-R2 to be all the various groups nor for 3) RB1 and RA1 phenyl ring to be further substituted. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make of use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

**1) The breadth of the claims:** The instant claims encompass many compounds with numerous substitutions. Claim 2 goes on for pages and pages.

“containing one heteroatom selected from the group consisting of N and S, wherein the aryl or heteroaryl ring is unsubstituted or substituted by one or more R groups, or substituted by one R3 group, or substituted by one R3 group and one R group;

or when taken together, RA~ and Rm form a fused 5 to 7 membered saturated ring, optionally containing one heteroatom selected from the group consisting of N and S, and unsubstituted or substituted by one or more R groups;

R is selected from the group consisting of:

halogen,  
hydroxy,  
alkyl,  
alkenyl,  
haloalkyl,  
alkoxy,  
alkylthio, and

-N(R9)2,

R3 is selected from the group consisting of:

-Z-R4,  
-Z-X'-R4,  
-Z-X'-Y-R4,  
-Z-X'-Y-X'-Y-R4, and

-Z-X'-Rs;

Y' is selected from the group consisting of:  
a bond,

-C(O)-,

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-C(S)-,  
-S(O)2-,

-S(O)2-N(Rs)-,

-- **S(O)2-** N~ --~

Rlo

-c(o)-o-,

-C(O)-N(Rs)-,

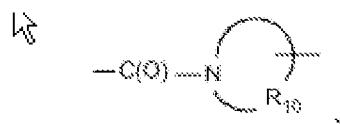
-C(S)-N(Rs)-,

-C(O)-N(Rs)-S(O)2-,

-C(O)-N(Rs)-C(O)-,

-C(S)-N(Rs)-C(O)-,

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- C(O)-C(O)-,
- C(O)-C(O)-O-, and
- C(=NH)-N(R<sub>3</sub>)-;

R<sub>1</sub> is selected from the group consisting of:

- R<sub>4</sub>,
- X'-R<sub>4</sub>,
- X'-Y'-R<sub>4</sub>,
- X'-Y'-X'-Y'-R<sub>4</sub>,
- X'-R<sub>5</sub>,
- X'-O-NR<sub>18</sub>-Y'-R<sub>19</sub>, and
- X'-O-N=C(R<sub>3</sub>') (R<sub>3</sub>'');

R<sub>18</sub>, R<sub>19</sub>, R<sub>1</sub>', R<sub>1</sub>'', R<sub>2</sub>, and R<sub>2</sub>'' are independently selected from the group consisting of:

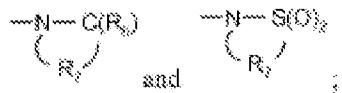
- hydrogen,
- alkyl,
- alkenyl,
- aryl,
- arylalkylenyl,
- heteroaryl,
- heteroarylalkylenyl,
- heterocyclyl,
- heterocyclylalkylenyl, and

alkyl, alkenyl, aryl, arylalkylenyl, heteroaryl, heteroarylalkylenyl, heterocyclyl, or heterocyclylalkylenyl, substituted by one or more substituents selected from the group consisting of:

- hydroxy,
- alkyl,
- haloalkyl,
- hydroxyalkyl,

alkoxy,  
dialkylamino,  
 $\text{-S(O)}_{0-2}\text{-alkyl}$ ,  
 $\text{-S(O)}_{0-2}\text{-aryl}$ ,  
 $\text{-NH-S(O)}_{0-2}\text{-alkyl}$ ,  
 $\text{-NH-S(O)}_{0-2}\text{-aryl}$ ,  
haloalkoxy,  
halogen,  
cyano,  
nitro,  
aryl,  
heteroaryl,  
heterocyclyl,  
aryloxy,  
arylalkyleneoxy,  
 $\text{-C(O)-O-alkyl}$ ,  
 $\text{-C(O)-N(R_8)_2}$ ,  
 $\text{-N(R_8)-C(O)-alkyl}$ ,  
 $\text{-O-(CO)-alkyl}$ , and  
 $\text{-C(O)-alkyl}$ ,

or  $R_{1a}$  and  $R_{1b}$  and/or  $R_2$  and  $R_{2a}$  together with the nitrogen atom and  $Y'$  to which they are bonded can join to form a ring selected from the group consisting of:

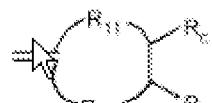


or  $R_7'$  and  $R_7''$  can join together to form a ring system selected from the group consisting of:

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wherein the total number of atoms in the ring is 4 to 9; and



wherein the total number of atoms in the ring is 4 to 9;

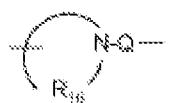
$R_1$  and  $R_2$  are independently selected from the group consisting of hydrogen, halogen, hydroxy, alkyl, alketyl, aryl, haloalkyl, alkoxy, alkylthio, and  $-N(R_3)_2$ ; or  $R_1$  and  $R_2$  can join to form a fused aryl ring or fused 5-10 membered heteroaryl ring containing one to four heteroatoms;

$X'$  is selected from the group consisting of alkylene, alkenylene, alkynylene, arylene, heteroarylene, and heterocyclylene wherein the alkylene, alkenylene, and alkynylene groups can be optionally interrupted or terminated by arylene, heteroarylene or heterocyclylene and optionally interrupted by one or more  $-O-$  groups;

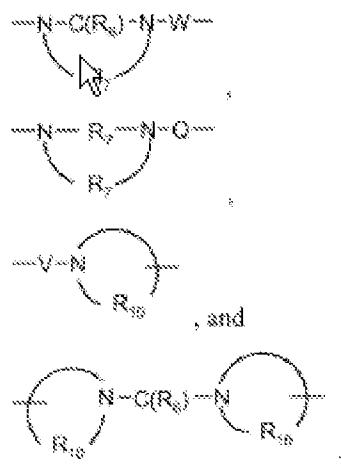
$X''$  is  $-CH(R_{13})$ -alkylene- or  $-CH(R_{13})$ -alkenylene-, wherein the alkylene and alkenylene are optionally interrupted by one or more  $-O-$  groups;

$Y$  is selected from the group consisting of:

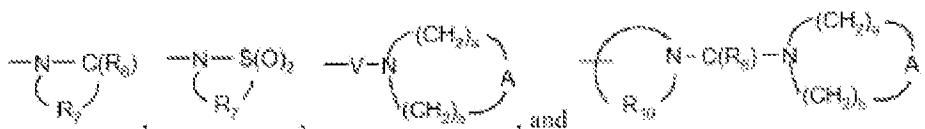
- $-S(O)_{2-2}$ ,
- $-S(O)_2-N(R_3)-$ ,
- $-C(R_3)-$ ,
- $-C(R_3)-O-$ ,
- $-O-C(R_3)-$ ,
- $-O-C(O)-O-$ ,
- $-N(R_3)-Q-$ ,
- $-C(R_3)-N(R_3)-$ ,
- $-O-C(R_3)-N(R_3)-$ ,
- $-C(R_3)-N(OR_3)-$ ,



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*Z* is a bond or  $\text{-O-}$ ;

*R<sub>4</sub>* is selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, aryl, arylalkyl, aryloxyalkyl, alkyfarylfenyl, heteraryl, heteroarylalkyl, heteroaryloxyalkyl, alkyheteroarylenyl, and heterocyclyl wherein the alkyl, alkenyl, alkynyl, aryl, arylalkyl, aryloxyalkyl, alkyfarylenyl, heteraryl, heteroarylalkyl, heteroaryloxyalkyl, alkyheteroarylenyl, and heterocyclyl groups can be unsubstituted or substituted by one or more substituents independently selected from the group consisting of alkyl, alkoxy, hydroxyalkyl, haloalkyl, haloalkoxy, halogen, nitro, hydroxy, mercapto, cyano, aryl, aryloxy, arylalkyleneoxy, heteraryl, heteroaryloxy, heteroarylalkyleneoxy, heterocyclyl, amino, alkylamino, dialkylamino, (dialkylamino)alkyleneoxy, and in the case of alkyl, alkenyl, alkynyl, and heterocyclyl, oxo;

*R<sub>5</sub>* is selected from the group consisting of:*R<sub>6</sub>* is selected from the group consisting of  $=\text{O}$  and  $=\text{S}$ ;*R<sub>7</sub>* is C<sub>2-7</sub> alkylenes;

*R<sub>8</sub>* is selected from the group consisting of hydrogen, C<sub>1-10</sub> alkyl, C<sub>2-15</sub> alkenyl, C<sub>1-10</sub> alkoxy-C<sub>1-10</sub> alkyl, and aryl-C<sub>1-10</sub> alkyl;

*R<sub>9</sub>* is selected from the group consisting of hydrogen and alkyl;*R<sub>10</sub>* is C<sub>3-5</sub> alkylenes;

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R<sub>13</sub> is C<sub>1-6</sub> alkylene or C<sub>2-8</sub> alkenylene, wherein the alkylene or alkenylene is optionally interrupted by one heteroatom;

R<sub>12</sub> is selected from the group consisting of a bond, C<sub>1-3</sub> alkylene, and C<sub>2-5</sub> alkenylene, wherein the alkylene or alkenylene is optionally interrupted by one heteroatom;

R<sub>11</sub> is selected from the group consisting of hydrogen and alkyl which may be optional interrupted by one or more -O- groups;

A is selected from the group consisting of -CH<sub>2-</sub>, -O-, -C(O)<sub>a</sub>-S(O)<sub>b-2</sub>, and -N(R<sub>4</sub>)-;

A' is selected from the group consisting of -O-, -S(O)<sub>b-2</sub>, -N(Q-R<sub>4</sub>)-, and -CH<sub>2-</sub>;

Q is selected from the group consisting of a bond, -C(R<sub>5</sub>)-, -C(R<sub>5</sub>)-C(R<sub>6</sub>)-, -S(O)<sub>2-</sub>, -C(R<sub>5</sub>)-N(R<sub>6</sub>)-W-, -S(O)<sub>2-</sub>N(R<sub>6</sub>)-, -C(R<sub>5</sub>)-O-, and -C(R<sub>5</sub>)-N(OR<sub>8</sub>)-;

V is selected from the group consisting of -C(R<sub>5</sub>)-, -O-C(R<sub>5</sub>)-, -N(R<sub>8</sub>)-C(R<sub>6</sub>)-, and -S(O)<sub>b-2</sub>;

W is selected from the group consisting of a bond, -C(O)-, and -S(O)<sub>2-</sub>; and

a and b are independently integers from 1 to 6 with the proviso that a + b is ≤ 7; or a pharmaceutically acceptable salt thereof.

**2) The nature of the invention:** The invention is a (highly) substituted tricyclic compound for treating viral disorders.

**3) The state of the prior art:** Similar compounds with some substitutents on a different position are known. WO 2005018551 and WO 2005018556

**4) The level of one of ordinary skill:** The ordinary artisan is highly skilled.

**5) The level of predictability in the art:**

There is a high level of unpredictability in the pharmaceutical art. One is with respect to how to use and the other is with respect to how to make them.

With regards how to use,

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be

individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18(CCPA

1970) indicates that the more unpredictable an area is, the more specific enablement is

necessary in order to satisfy the statute. The level of unpredictability in the art is very high.

The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodilator and they differ only by a methyl group.

With regards how to make ;-

As stated in the preface to a recent treatise:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work .....Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)

....." Dorwald F. A.

**6) The amount of direction provided by the inventor:** The inventor provides very little direction in the instant specification. Only specific examples are given

**7) The existence of working examples:** The instant specification has limited number of examples with respect to the % of the claimed invention.

**8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:** Since there are limited working examples, the amount of experimentation is very high and burdensome.

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention.

The specification gives literally no guidance with regard to what the requirements for activity are i.e. which substituents would be preferred. See *Ex parte Herzog, Hershberg, and Coan*, 115 USPQ 195 (Bd. Pat. App. & Int. 1956) affirming the examiner, and stating "it becomes obvious that the expressions defining the organic acids used.....are inclusive of inoperative materials and go far beyond the adequately disclosed subject matter of the specification." And also *Ex parte DIAMOND*, 123 USPQ 167 (Bd. Pat. App. & Int. 1959) where the examiner was affirmed for a scope of enablement rejection, and the court stated:

Scope of claims should not be unduly extensive in chemical fields where applicability is highly speculative or not explored; subject matter which relies upon prediction for its support is unpatentable.

Specification contains 23 specific examples, but they are to preparation of relatively simple compounds; this is relatively meager and non representative disclosure to support claims embracing millions of compounds.

Applicant may not preempt unduly large field by expedient of making broad prophetic statements in specification and claims unless accuracy of such statements is sufficiently supported by well established chemical principles or by sufficient number of examples. "The term 'substituted' without modification or restriction includes all compounds wherein one or more of the atoms or radicals of the original compound have been replaced by one or more other atoms or radicals. Without any limitation on the character or number of substituents it becomes apparent that the quoted term may be considered inclusive of almost any possible substance and the claims under consideration are either of unlimited or indeterminate scope. We are of the opinion that the reasoning of the courts in *Schering Corp. v. Gilbert*, 68 USPQ 84, and *Hercules Powder Co. v. Rohm & Haas*, 70 USPQ 297, is controlling."

embrace millions of compounds. It should also be observed that appellant is working in a field where little prediction is possible and this Board has on several occasions held that the scope of claims should not be unduly extensive in fields where applicability is highly speculative or not explored and that subject matter which relies upon prediction for its support is unpatentable. *Ex parte Middleton*, 87 USPQ 57; *Ex parte Kauck et al.*, 95 USPQ 197 , *Ex parte Rosenkranz et al.*, Pat. No. 2,715,637.

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In Minnesota Mining and Mfg. Co. et al. v. Carborundum Co. et al., 155 F.2d 746, 69 USPQ 288 , the court held that “An inventor cannot disclose a small number of components which will serve as a springboard for claiming an entire class.”

In addition *In re Fouche* 169 USPQ 429 dealt with a similar issue with respect to how to use requirement of 112 1<sup>st</sup> paragraph,

“Inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention; nevertheless, applicant must use some technique of providing teaching of how to use which is commensurate with breadth of protection sought by claim, unless such knowledge is already available to persons skilled in the art; thus, where applicant undertakes to define invention by recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of group.

Both the examiner and the board noted that none of the working examples pertained to compounds wherein Z was heterocyclic. Appellant is quite correct in contending that, under our decisions in *In re Robins*, 57 CCPA 1321, 429 F.2d 452, 166 USPQ 552 (1970), the inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use *some* technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

It seems clear, and it is not disputed by appellant, that where an applicant undertakes to define his invention by the recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of the Markush group. The examiner and the board did not believe that appellant had done so as to the heterocyclic members of the group. While they noted the absence of examples using heterocyclic moieties, we do not find that they viewed examples as mandatory. The issue before us is whether appellant has provided *any* teaching of how to use compounds containing the heterocyclic members of the Markush group. The only reference to heterocyclic radicals in the specification is the statement that “the invention provides” compounds of the structure shown in claim 1, wherein Z may be, among other possibilities, a mononuclear, nitrogen-containing heterocycle connected to the chain A by the nitrogen atom, and optionally containing an oxygen, sulphur, or second nitrogen atom in the ring and optionally substituted by one of more alkyl radicals containing 1 to 5 carbon atoms each, such as 1-pyrrolidyl, piperidino, morpholino, 1-piperazinyl, or 4-alkyl-1-piperazinyl. “

See *Ex parte WEIL AND SCHLICHTING*, 158 USPQ 620 (Bd. Pat. App. & Int. 1967)

“We will sustain this rejection of the claims as we are in accord with the examiner's position. We find no support in the disclosure for such compounds encompassed by these claims wherein R 1, R 2, R 3, and R 5are all the same and selected from the group, lower alkyl , hydroxy , alkoxy , di(loweralkyl)amino and nitro for example. These claims appear to be in the nature of a paper concept wherein all possible substituents have been included in the

composition. There are no examples of such compounds which are included within the vast scope encompassed by these claims, although appellants have a considerable disclosure with respect to certain components but this does not warrant claims of the enormous breadth recited.”

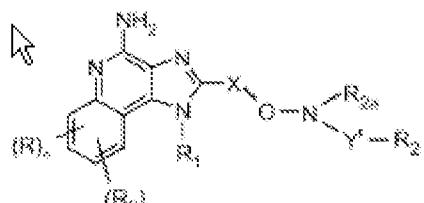
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are rejected under 35 U.S.C. 103(a) as being obvious over WO 2005018556. (and WO200501551 ) The applied reference has a common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

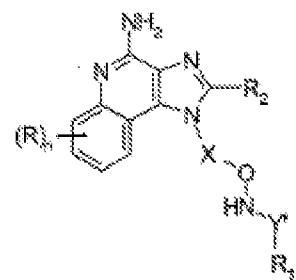
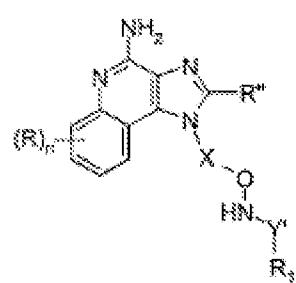
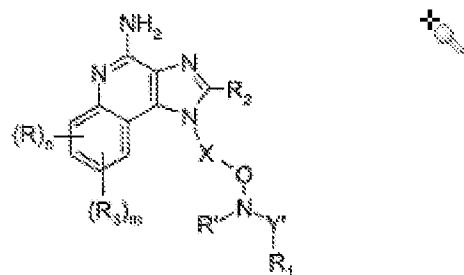
Applicants compounds are drawn to tricyclic imidazoquinolines of the formula



IIIa

Scope and Content of the Prior Art.

The WO 2005018556 teaches the compounds which are very similar but are positional isomers. The hydroxylamine substituent is at a different position.



*Difference between Prior Art and the claims MPEP 2141.02*

The hydroxylamine substituent is at a different position on the imidazole, making it a positional isomers.

Prima Facie Obviousness and Rational.

One of skill in the art would have been motivated to make similar compounds with substitution at a different position on the same core and still expect the compounds to retain its properties.

The same reasoning applies to WO 2005048933, WO 2005051324 ( it clearly teaches the equivalence of the oxime and the hydroxylamine)

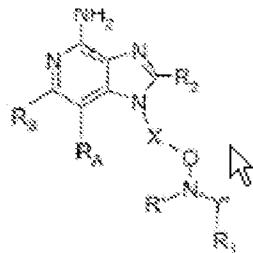
### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S.application 11/595058 Patent No. not yet known . Although the conflicting claims are not identical, they are not patentably distinct from each other because because these claims are also



drawn to compounds of the formula wherein Ra and RB both form a six membered ring.

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 31 of copending Application No. 10/595065. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to similar core with oxime substituents. This differs only in a H at the N. and besides WO 2005051324 teaches the equivalence of the oxime and hydroxylamine, see page 5 , lines 6-9. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1 of copending Application No 10/595058 (US 20080114019)

Claim 1 of application number 11/884153 US 20090062328 and claim 1 of US 2009004295 10/595792 . Although the conflicting claims are not identical, they are not patentably distinct from each other because 11884,153 teach both the hydroxylamine and the oximes and 10/595792 and 10/595058 are similar compounds for the same use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

Claims 2, 4, 5, 14, 19-29, 35, 39, 40-49, 65 and 66 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/  
Primary Examiner, Art Unit 1625

October 23, 2009.